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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/177,814 10/23/98 GILTON

T 3530US (97-12

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HM22/1010

EXAMINER

GABEL, G

ART UNIT

PAPER NUMBER

1641

DATE MAILED:

10/10/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/177,814

Applicant(s)

GILTON, TERRY L.

Examiner

Gailene R. Gabel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 July 2001.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-11,13-44,46,48-64,66-74 and 105-107 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-11,13-44,46,48-64,66-74 and 105-107 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Amendment Entry

1. Applicant's amendment and response filed 7/30/01 in Paper No. 17 is acknowledged and has been entered. Claims 1, 30, 51, and 64 have been amended. Currently, claims 1, 3-11, 13-44, 46, 48-64, 66-74 and 105-107 are pending and under examination.

Rejections Maintained

Claim Rejections - 35 USC § 103

2. Claims 105-107 are rejected under 35 U.S.C. 103(a) as being unpatentable over Isaka et al. (US 5,482,598) in view of Turner et al. (US 5,885,869) for reasons of record.
3. Claims 1, 3-5, 7-11, 13, 16, 18-20, 25-26, 29-32, 34-35, 38-39, 43, 46, 48-53, 56, 64, 66, 69-71, and 73 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Isaka et al. (US 5,482,598) in view of Overton et al. (US 5,611,846) for reason of record.
4. Claims 14-15, 17, 21, 40-41, 44, and 54-55 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Isaka et al. (US 5,482,598) in view of Overton et al. (US 5,611,846) as applied to claims 1, 3-5, 7-11, 13, 16, 18-20, 25-26, 29-32, 34-35, 38-39, 43, 46, 48-53, 56, 64, 66, 69-71, and 73 above, and further in view of Miura et al. (US 5,132,012) for reason of record.

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5. Claims 21 and 41 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Isaka et al. (US 5,482,598) in view of Overton et al. (US 5,611,846) as applied to claims 1, 3-5, 7-11, 13, 16, 18-20, 25-26, 29-32, 34-35, 38-39, 43, 46, 48-53, 56, 64, 66, 69-71, and 73 above, and further in view of Wang et al. (US 5,663,488) for reason of record.

6. Claims 33 and 74 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Isaka et al. (US 5,482,598) in view of Overton et al. (US 5,611,846) as applied to claims 1, 3-5, 7-11, 13, 16, 18-20, 25-26, 29-32, 34-35, 38-39, 43, 46, 48-53, 56, 64, 66, 69-71, and 73 above, and further in view of Turner et al. (US 5,885,869) for reason of record.

7. Claims 22-24, and 42 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Isaka et al. (US 5,482,598) in view of Overton et al. (US 5,611,846) as applied to claims 1, 3-5, 7-11, 13, 16, 18-20, 25-26, 29-32, 34-35, 38-39, 43, 46, 48-53, 56, 64, 66, 69-71, and 73 above, and further in view of Northrup et al. (US 5,882,496) for reason of record.

8. Claims 27-28, 36-37, and 67-68 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Isaka et al. (US 5,482,598) in view of Overton et al. (US 5,611,846) as applied to claims 1, 3-5, 7-11, 13, 16, 18-20, 25-26, 29-32, 34-35, 38-39, 43, 46, 48-53, 56, 64, 66, 69-71, and 73 above, in further view of Swedberg et al. (US 5,571,410) for reason of record.

9. Claims 6, 57-63, and 72 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Isaka et al. (US 5,482,598) in view of Overton et al. (US 5,611,846)

as applied to claims 1, 3-5, 7-11, 13, 16, 18-20, 25-26, 29-32, 34-35, 38-39, 43, 46, 48-53, 56, 64, 66, 69-71, and 73 above, and if necessary, Northrup et al. (US 5,882,496), in view of Turner et al. (US 5,885,869) and in further view of Sunzeri (US 5,536,382) for reason of record.

Response to Arguments

10. Applicant's arguments filed 7/30/01 have been fully considered but they are not persuasive.

11. A) Applicant argues that Turner et al. which qualifies under a 35 USC 102 (e) rejection, does not qualify as prior art under 35 USC 103 (a) rejection. Specifically, Applicant argues that Turner which did not issue until 3/23/99 is commonly owned by Micron Technology to which the instant application is also assigned.

Based upon the earlier effective U.S. filing date, the Turner reference constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the

application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(I)(1) and § 706.02(I)(2).

B) Applicant argues that one of ordinary skill would not have been motivated to combine the teachings of Isaka with that of Overton. Specifically, Applicant argues that multiple columns on the gas chromatograph taught by Overton are connected to one another by pneumatic valves, and therefore cannot be structurally combinable with the extremely small scale silicon substrate chromatograph of Isaka.

In response, the miniaturized portable gas chromatograph taught by Overton has different specific configurations to fit intended uses such as the incorporation of two parallel different columns in an analyzer module each with corresponding detectors alongside thereto or such as in Figure 2(b) which illustrates multiple different injectors and extractors in sample processing modules for different multiple columns each fabricated with detectors in the analyzing modules of the apparatus (see column 9, lines 30-46). In column 9, lines 10-14, Overton only discloses a configuration which exemplifies that columns in the chromatograph can be connected via pneumatic valves. Overton was incorporated with the teaching of Isaka of a chromatograph apparatus comprising a microchannel element formed on a semiconductor substrate which

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comprises of silicon with increased pore size and extended branching of the pores on the surface which has incorporated thereto a capture substrate which is an **immobilized** enzyme, to effect separation based on the affinity of a constituent with the capture substrate. In column 3, lines 10-11, Isaka specifically discloses that "uricase is immobilized in the porous channel to check (by capturing and detecting) the amount of uric acid in serum" in the sample- and the constituent (uric acid) is separated by "capture" of the uric acid analyte by the affinity species (uricase) in the matrix, then the reaction product is detected.

Therefore, one of ordinary skill in the art at the time of the instant invention would have reasonable expectation of success in incorporating multiple separation columns such as taught by Overton into the miniaturized chromatograph apparatus such as taught by Isaka because Overton specifically taught that multiple columns in various configurations for different intended applications can be incorporated into his chromatograph apparatus suggesting that fabrication and use of multiple columns in separation chromatographs is well within ordinary skill. The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

C) Applicant argues that one of ordinary skill would not have been motivated to combine the teachings of Isaka and Overton with Miura and that there is no reasonable expectation of success in so doing. Applicant argues that Isaka, Overton, and Miura fail to teach a memory device on the substrate, a vacuum source in operative communication with a porous region, and that Miura only teaches use of positive pressure to facilitate movement of a sample.

In response, Overton and Miura each include a memory device in their chromatograph apparatus. The memory device as recited in claim 17 does not exclude those embodiments disclosed by Overton and Miura. Alternatively, Overton and Miura does not exclude disposing the memory device into the substrate of the device. Further, Miura teaches and suggest a migration facilitator comprising a pump that is fed under positive pressure into the feed pump to facilitate movement of the sample (column 4, lines 4-59) Alternatively, claims 21 and 41 do not appear to exclude use of positive pressure in facilitating migration of the samples through the columns.

D) Applicant argues that one of ordinary skill would not have been motivated to combine the teachings of Isaka and Overton with Wang and that there is no reasonable expectation of success in so doing. Applicant argues that Isaka, Overton, and Wang fail to teach a vacuum source that is operatively in communication with an end of the chromatography column.

In response, Wang was incorporated with the teachings of both Isaka and Overton for his disclosure of a vacuum (or near vacuum) source for use in altering the

concentration of gas within cavities of the separation column. Alternatively, claims 21 and 41 do not appear to exclude use of such vacuum taught by Wang in facilitating migration of the samples through the claimed column.

E) Applicant argues that one of ordinary skill would not have been motivated to combine the teachings of Isaka and Overton with Turner and that there is no reasonable expectation of success in so doing. Specifically, Applicant argues that Turner only qualifies under a 35 USC 102 (e) rejection but does not qualify in a 35 USC 103 (a) rejection.

Based upon the earlier effective U.S. filing date, the Turner reference constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned

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by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(I)(1) and § 706.02(I)(2).

F) Applicant argues that one of ordinary skill would not have been motivated to combine the teachings of Isaka and Overton with Northrup and that there is no reasonable expectation of success in so doing. Applicant argues Northrup does not remedy the deficiencies of Isaka and Overton.

In response, the miniaturized portable gas chromatograph of Overton includes multiple different injectors and extractors in sample processing modules for different multiple columns each fabricated with detectors in the analyzing modules of the apparatus. Overton was incorporated with the teaching of Isaka of a chromatograph apparatus comprising a microchannel element formed on a semiconductor substrate which comprises of silicon with increased pore size and extended branching of the pores on the surface which has incorporated thereto a capture substrate.

Therefore, one of ordinary skill in the art at the time of the instant invention would have reasonable expectation of success in incorporating electrodes such as taught by Northrup into the miniaturized apparatus taught by Isaka which may include multiple separation columns such as suggested by Overton because Northrup specifically taught that electrodes can be disposed into miniaturized porous silicon structures such as in electrophoresis devices suggesting that incorporation of electrophoretic elements in separation chromatographs is well within ordinary skill.

G) Applicant argues that one of ordinary skill would not have been motivated to combine the teachings of Isaka and Overton with Swedberg and that there is no reasonable expectation of success in so doing. Applicant argues Swedberg does not remedy the deficiencies of Isaka and Overton.

In response, the miniaturized portable gas chromatograph of Overton includes multiple different injectors and extractors in sample processing modules for different multiple columns each fabricated with detectors in the analyzing modules of the apparatus. Overton was incorporated with the teaching of Isaka of a chromatograph apparatus comprising a microchannel element formed on a semiconductor substrate which comprises of silicon with increased pore size and extended branching of the pores on the surface which has incorporated thereto a capture substrate.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the stationary phase in the porous matrix of the chromatographic separation apparatus taught by Isaka, which may include multiple separation columns such as suggested by Overton, with antigens and antibodies as taught by Swedberg in order to achieve performance of both filtration and capture function because Swedberg specifically suggested potential application of his teachings in monitoring biological analyses as applied to liquid phase separation devices in the miniature scales such as taught by Isaka. One of ordinary skill in the art would have been motivated to incorporate the teachings of Isaka with biocompatible modification as taught by Swedberg because Isaka specifically taught that porous silicon has established porosity with enhanced capacity for separation, augmented adsorption, differentiation of flow

rate in liquid or gaseous samples, thereby producing a highly versatile miniaturized chromatographic device capable of both enhanced partitioning and complexation reactions.

H) Applicant argues that one of ordinary skill would not have been motivated to combine the teachings of Isaka and Overton with Northrup, Turner and Sunzeri and that there is no reasonable expectation of success in so doing. Applicant argues Northrup, Turner and Sunzeri do not remedy the deficiencies of Isaka and Overton. Specifically, Overton teaches an apparatus that includes open-channeled chromatography columns which are free standing and in a substrate.

In response, the miniaturized portable gas chromatograph of Overton includes multiple different injectors and extractors in sample processing modules for different multiple columns each fabricated with detectors in the analyzing modules of the apparatus. Overton was incorporated with the teaching of Isaka of a chromatograph apparatus comprising a microchannel element formed on a semiconductor substrate which comprises of silicon with increased pore size and extended branching of the pores on the surface which has incorporated thereto a capture substrate.

Sunzeri discloses quantitation using internal and external standards in assays where the sample matrix affects fluorescence sample quenching (column 10, lines 1-34).

One of ordinary skill in the art would have reasonable expectation of success in incorporating internal standards or controls such as suggested by Sunzeri into the

12. No claims are allowed.

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.


14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R. Gabel whose telephone number is (703) 305-0807. The examiner can normally be reached on Monday to Thursday from 7:00

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AM to 4:30 PM. The examiner can also be reached on alternate Fridays from 7:00 AM to 3:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (703) 305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


10-8-01
Gailene R. Gabel
Patent Examiner
Art Unit 1641


LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600
10/09/01